NOT FOR PUBLICATION

UNITED STATES DISTRICT COURT
DISTRICT OF NEW JERSEY

HOFFMANN-LA ROCHE INC., Plaintiff, v. APOTEX INC. and APOTEX CORP., Defendants.	Civil Action No. 07-4417 (SRC) (MAS) Civil Action No. 08-3065 (SRC) (MAS) Civil Action No. 08-4053 (SRC) (MAS) (consolidated with 07-4417 for all purposes) **OPINION**
HOFFMANN-LA ROCHE INC., Plaintiff, v. COBALT PHARMACEUTICALS INC., and COBALT LABORATORIES, INC., Defendants.	Civil Action No. 07-4539 (SRC) (MAS) Civil Action No. 07-4540 (SRC) (MAS) Civil Action No. 08-4054 (SRC) (MAS) (consolidated with 07-4539 for all purposes)

CHESLER, U.S.D.J.

This matter comes before the Court on the motion for summary judgment, pursuant to Federal Rule of Civil Procedure 56, that Defendants infringe the '814 patent by Plaintiff Hoffman-La Roche Inc. ("Roche"), against Defendants Cobalt Pharmaceuticals Inc. and Cobalt Laboratories, Inc. (collectively, "Cobalt") and Apotex Inc. and Apotex Corp. (collectively, "Apotex"). For the reasons stated below, Roche's motion will be granted.

BACKGROUND

This matter involves several Hatch-Waxman actions for patent infringement. The cases have been consolidated for pretrial purposes and arise from the following facts. Briefly, Roche

owns U.S. Patent No. 4,927,814 (the "'814 patent"), which is directed to certain disphosphonate compounds, pharmaceutical compositions and methods of use of same, and which includes ibandronic acid, the active ingredient in Roche's osteoporosis drug Boniva®. Defendants are generic pharmaceutical manufacturers who have filed Abbreviated New Drug Applications seeking FDA approval to engage in the manufacture and sale of generic versions of Boniva® prior to the expiration of Roche's patent.

ANALYSIS

I. Relevant legal standards

A. Motions for summary judgment

Summary judgment is appropriate under FED. R. CIV. P. 56(c) when the moving party demonstrates that there is no genuine issue of material fact and the evidence establishes the moving party's entitlement to judgment as a matter of law. Celotex Corp. v. Catrett, 477 U.S. 317, 322-23 (1986). A factual dispute is genuine if a reasonable jury could return a verdict for the non-movant, and it is material if, under the substantive law, it would affect the outcome of the suit. Anderson v. Liberty Lobby, Inc., 477 U.S. 242, 248 (1986). "In considering a motion for summary judgment, a district court may not make credibility determinations or engage in any weighing of the evidence; instead, the non-moving party's evidence 'is to be believed and all justifiable inferences are to be drawn in his favor.'" Marino v. Indus. Crating Co., 358 F.3d 241, 247 (3d Cir. 2004) (quoting Anderson, 477 U.S. at 255).

"When the moving party has the burden of proof at trial, that party must show affirmatively the absence of a genuine issue of material fact: it must show that, on all the essential elements of its case on which it bears the burden of proof at trial, no reasonable jury

could find for the non-moving party." In re Bressman, 327 F.3d 229, 238 (3d Cir. 2003) (quoting United States v. Four Parcels of Real Property, 941 F.2d 1428, 1438 (11th Cir. 1991)). "[W]ith respect to an issue on which the nonmoving party bears the burden of proof . . . the burden on the moving party may be discharged by 'showing' – that is, pointing out to the district court – that there is an absence of evidence to support the nonmoving party's case." Celotex, 477 U.S. at 325.

Once the moving party has satisfied its initial burden, the party opposing the motion must establish that a genuine issue as to a material fact exists. Jersey Cent. Power & Light Co. v. Lacey Township, 772 F.2d 1103, 1109 (3d Cir. 1985). The party opposing the motion for summary judgment cannot rest on mere allegations and instead must present actual evidence that creates a genuine issue as to a material fact for trial. Anderson, 477 U.S. at 248; Siegel Transfer, Inc. v. Carrier Express, Inc., 54 F.3d 1125, 1130-31 (3d Cir. 1995). "[U]nsupported allegations . . . and pleadings are insufficient to repel summary judgment." Schoch v. First Fid. Bancorporation, 912 F.2d 654, 657 (3d Cir. 1990); see also FED. R. CIV. P. 56(e) (requiring nonmoving party to "set out specific facts showing a genuine issue for trial"). "A nonmoving party has created a genuine issue of material fact if it has provided sufficient evidence to allow a jury to find in its favor at trial." Gleason v. Norwest Mortg., Inc., 243 F.3d 130, 138 (3d Cir. 2001).

If the nonmoving party has failed "to make a showing sufficient to establish the existence of an element essential to that party's case, and on which that party will bear the burden of proof at trial, . . . there can be 'no genuine issue of material fact,' since a complete failure of proof concerning an essential element of the nonmoving party's case necessarily renders all other facts

immaterial." Katz v. Aetna Cas. & Sur. Co., 972 F.2d 53, 55 (3d Cir. 1992) (quoting Celotex, 477 U.S. at 322-23).

B. Literal infringement

The test for patent infringement requires a two step analysis: "the claim scope is first determined, and then the properly construed claim is compared with the accused device to determine whether all of the claim limitations are present either literally or by a substantial equivalent." Amazon.com, Inc. v. Barnesandnoble.com, Inc., 239 F.3d 1343, 1350-1351 (Fed. Cir. 2001). "To prove direct infringement, the plaintiff must establish by a preponderance of the evidence that one or more claims of the patent read on the accused device literally or under the doctrine of equivalents. Literal infringement requires that each and every limitation set forth in a claim appear in an accused product." Cross Med. Prods., Inc. v. Medtronic Sofamor Danek, Inc., 424 F.3d 1293, 1310 (Fed. Cir. 2005) (internal citations omitted). Although claim construction is an issue of law, the determination of infringement is a question of fact. Pause Tech. LLC v. TiVo Inc., 419 F.3d 1326, 1329 (Fed. Cir. 2005).

II. Roche's motion for summary judgment

Roche's motion concerns claim 4 of the '814 patent:

> 4. The diphosphonate compound of claim 1 designated 1-hydroxy-3-(N-methyl-N-pentylamino)-propane-1,1-diphosphonic acid and the physiologically active salt thereof.

Roche contends that it is entitled to summary judgment of infringement because the active ingredient in the products proposed in Defendants' ANDAs, ibandronate sodium, is a physiologically active salt of 1-hydroxy-3-(N-methyl-N-pentylamino)-propane-1,1-diphosphonic acid. The parties do not dispute the essential underlying facts: the ANDAs propose that the

active ingredient is ibandronate sodium, which is a salt of 1-hydroxy-3-(N-methyl-N-pentylamino)-propane-1,1-diphosphonic acid. There is also no dispute that the ANDAs propose that ibandronate sodium will, upon ingestion, have physiological effects.

Defendants' principal argument in opposition is that ibandronate sodium is not a physiologically active salt. This argument is premised on undisputed facts about the sequence of events which occur during the treatment process: 1) prior to ingestion, ibandronate sodium exists as a compound; 2) at some point after ingestion, the body acts upon ibandronate sodium and dissolves it; 3) when ibandronate sodium is dissolved, it dissociates into the ibandronate anion and the sodium cation; and 4) it is the ibandronate anion that acts upon the body and produces the physiological effects. Again, the parties do not dispute these basic facts.

Defendants contend that, because it is the ibandronate anion that produces the physiological effects at the last step of this process, and not the ibandronate sodium that exists at the first step, which is the salt form, ibandronate sodium is not a physiologically active salt, within the meaning of claim 4, and does not literally infringe.

Roche counters that Defendants are improperly rearguing claim construction. This Court agrees. Defendants do not dispute the underlying facts but, rather, the meaning of the claim language, "physiologically active salt." This Court has already held a Markman proceeding to construe the meaning of the phrase "physiologically active salt," and it issued a claim construction Opinion on May 7, 2010, which stated:

> Apotex and Cobalt propose that the phrase "physiologically active salt," appearing in claim 4, should be construed to mean: "A solid substance in which the salt ion provides its own active effect, separate and apart from any drug component that

> may be included as an anion within the final salt product." Roche proposes that this phrase should be construed to mean: "a salt form of ibandronic acid that is physiologically active, i.e., capable of producing physiological activity."
>
> In short, Apotex and Cobalt's argument consists of these statements: "A person of ordinary skill in the art would recognize that the term 'physiologically active' when applied to the term 'salt' requires a salt component that itself produces an intended physiological effect, separate and apart from any effect caused by the drug component itself (here ibandronate). . . [A] physiologically active salt is a solid product in which the salt cation has activity additional to that provided by the drug anion with which it is associated in a solid." (Apotex and Cobalt Br. 16.)

(Opinion of May 7, 2010 at 9-10.) This Court concluded: "Roche has correctly construed the phrase to mean a salt of ibandronic acid that is physiologically active." (Id. at 11.)

In the claim construction Opinion, this Court was guided by the Federal Circuit's instruction that, in construing claims, courts should consider what the inventor actually invented:

> In Phillips, the Federal Circuit instructed courts to consider what the inventor actually invented. The Court quoted Renishaw PLC v. Marposs Societa' per Azioni, 158 F.3d 1243, 1250 (Fed. Cir. 1998)), as follows:
>
> > Ultimately, the interpretation to be given a term can only be determined and confirmed with a full understanding of what the inventors actually invented and intended to envelop with the claim. The construction that stays true to the claim language and most naturally aligns with the patent's description of the invention will be, in the end, the correct construction.
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> Phillips, 415 F.3d at 1316.

(Opinion of May 7, 2010 at 10-11 n.6.) This bears repeating because Defendants' argument can only succeed if this Court forgets about what the inventor actually invented. There is no question about what the inventor invented: ibandronic acid in various forms which are used for the treatment or prophylaxis of calcium metabolism disturbance or disease. This Court construes the phrase "physiologically active salt" in the way that best captures what the inventor invented.

Defendants, on the other hand, seek to construe "physiologically active salt" in a way that subverts the Federal Circuit's guidance in Phillips and Renishaw. There is no reason to believe – and Defendants have not even suggested this – that the inventor invented a salt form of ibandronic acid that, after ingestion, having resisted digestion and dissolution, passes into the blood stream untouched, and has a therapeutic effect while in its pristine, undissolved state. Even if, for the sake of discussion, this Court were to allow Defendants to redo the claim construction on the fly – which it does not intend to do – this Court would not conclude that Defendants' present construction of "physiologically active salt" captures what the inventor actually invented.

Furthermore, Defendants' proposed construction has the problematic effect of making the claim invalid. Consider, for the sake of discussion, if Defendants were correct, and the phrase "physiologically active salt" were construed as implying a limitation to those pharmaceuticals that resist digestion and pass into the bloodstream unchanged, where they have their final therapeutic effect in an unchanged form. There is no dispute that, in fact, ibandronate sodium dissolves in the body. Cobalt, for example, lays out the evidence of this at length. (See, e.g., Cobalt's 56.1 Counterstmt. ¶¶ 120-176.) Cobalt quotes its expert, Dr. Gould, as follows:

> 162. Dr. Gould has explained that salts, like ibandronate sodium, "would necessarily have to dissolve in the fluids of the gastrointestinal tract in order for the drug to be available for absorption." (Raghavan Decl. Ex. 4, Gould Report ¶ 28).

(Id. at ¶ 162.) If this is true – and no one appears to be disputing it –, and salts like ibandronate sodium necessarily must dissolve in the fluids of the gastrointestinal tract in order for the drug to be available for absorption into the body, then Defendants have proposed that the patentee

claimed an impossible invention. If this is true, and "physiologically active salt" means what Defendants contend, then no physiologically active salt can possibly exist as an orally administered pharmaceutical, because it is physiologically impossible. Such a claim fails because the subject matter is inoperable: "[W]hen a claim requires a means for accomplishing an unattainable result, the claimed invention must be considered inoperative as claimed and the claim must be held invalid under either § 101 or § 112 of 35 U.S.C." Raytheon Co. v. Roper Corp., 724 F.2d 951, 956 (Fed. Cir. 1983); see also Process Control Corp. v. HydReclaim Corp., 190 F.3d 1350, 1359 (Fed. Cir. 1999) ("when an impossible limitation . . . such as a nonsensical method of operation, is clearly embodied within the claim, the claimed invention must be held invalid.")

The Federal Circuit has stated that it is a "familiar axiom that claims should be so construed, if possible, as to sustain their validity." Liebel-Flarsheim Co. v. Medrad, Inc., 358 F.3d 898, 911 (Fed. Cir. 2004). Defendants propose a construction that would render the claim inoperable and invalid. Plaintiff's construction, on the other hand, preserves the claim's validity. This Court previously ruled on the claim construction of "physiologically active salt" and offers this commentary now only to provide belt and suspenders for its rejection of Defendants' new claim construction argument.

The claim construction that this Court stated in its Opinion of May 7, 2010 remains the one that will be used in this infringement analysis. This Court accepted Roche's proposed construction. Roche proposed that "physiologically active salt" means a salt form of ibandronic acid that is capable of producing physiological activity. Defendants seek to further narrow this construction, as if it meant, "capable of producing physiological activity without dissolution."

This impermissibly narrows the Court's claim construction; the only limitation is that the salt must be capable of producing physiological activity. Ibandronate sodium is a salt and it is capable of producing physiological activity. Were this not the case, it would mean that Defendants have applied to the FDA for permission to manufacture something that is incapable of having a pharmaceutical effect. Clearly, Defendants believe that ibandronate sodium is capable of producing a physiological effect, or they would not have sought permission to manufacture and sell it for the treatment of osteoporosis.

Furthermore, even if this Court did not reject Defendants' proposed construction for the substantive reasons just stated, as a matter of procedural fairness, it would be reluctant to be receptive to Defendants' change in position. As the Court stated in the claim construction Opinion, Defendants proposed a construction of "physiologically active salt" in which both the anion and the cation have independent physiological effects. Now, Defendants seek to rely on a construction in which the anion and the cation have physiological effects only in combination. To allow Defendants to succeed with this change in position seems both unfair and untimely.

Apotex also argues that it is Roche that now seeks to disavow the very claim construction that it sought, and in so doing Apotex seeks to turn the situation on its head. This Court did not, as Apotex contends, hold that the physiological activity must be produced by the whole salt molecule, prior to dissolution. As discussed above, this Court now employs in this infringement analysis the same claim construction it previously established. Moreover, if Apotex believed that the claim construction Opinion left a key issue unresolved, it should have moved for reconsideration to bring the issue to the Court's attention. It did not do so.

Apotex also opposes Roche's motion with the argument that they cannot infringe claim 4

because claim 4 depends on claim 1, and claim 1 "recites nonsense." (Apotex Opp. Br. 14.) As Roche observes, this Court need not enter the thicket of the intelligibility of claim 1. Even though claim 4 does depend on claim 1, claim 4 can be understood completely clearly without any reference to claim 1. Claim 4 specifies that the compound from claim 1 that it refers to is 1-hydroxy-3-(N-methyl-N-pentylamino)-propane-1,1-diphosphonic acid. Apotex does not argue that this part of claim 4 is nonsense. As the Court observed in its claim construction Opinion, the parties have essentially agreed that this formula refers to ibandronic acid. (Opinion of May 7, 2010 at 6.) There is no question as to the meaning of 1-hydroxy-3-(N-methyl-N-pentylamino)-propane-1,1-diphosphonic acid in claim 4.

Furthermore, there are problems with the argument that claim 1 is nonsense. Apotex does not argue that claim 4 is invalid, and this Court questions how the argument that claim 1 is nonsense is relevant in the absence of raising claim 4's invalidity as an affirmative defense to its infringement. Even if, however, Apotex had challenged the validity of claim 4, it would still be possible to arrive at a ruling on infringement. The Federal Circuit has stated:

> [P]atent infringement and invalidity are separate and distinct issues. Though an invalid claim cannot give rise to liability for infringement, whether it is infringed is an entirely separate question capable of determination without regard to its validity.

Pandrol USA, LP v. Airboss Ry. Prods., 320 F.3d 1354, 1365 (Fed. Cir. 2003) (citation omitted). Thus, this Court may rule on the issue of infringement without having to address a validity challenge.

This Court rejects Defendants' arguments as to the meaning of "physiologically active salt." Furthermore, Defendants have failed to show that any material factual disputes preclude

the entry of judgment as a matter of law. Roche has shown that the active ingredient in the products proposed in Defendants' ANDAs, ibandronate sodium, is a physiologically active salt of 1-hydroxy-3-(N-methyl-N-pentylamino)-propane-1,1-diphosphonic acid, and that Defendants' ANDAs propose products that will infringe claim 4 of the '814 patent. Roche's motion for summary judgment of infringement will be granted.

CONCLUSION

For the reasons stated above, Roche has shown that it is entitled to judgment as a matter of law. Roche's motion for summary judgment of infringement is granted, and Judgment on this claim is entered in Roche's favor.

s/ Stanley R. Chesler
Stanley R. Chesler, U.S.D.J.

Dated: August 24, 2010